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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|-----------------------|
| 10/705,719 | 11/10/2003 | Steve Cote | 14485.0156US01 | 4984 |
| 23552 | 7590 | 01/23/2009 | EXAMINER | |
| MERCHANT & GOULD PC P.O. BOX 2903 MINNEAPOLIS, MN 55402-0903 | | | | KOHARSKI, CHRISTOPHER |
| ART UNIT | | PAPER NUMBER | | |
| 3763 | | | | |
| | | MAIL DATE | | DELIVERY MODE |
| | | 01/23/2009 | | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|-------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/705,719 | COTE ET AL. | |
| | Examiner | Art Unit | |
| | CHRISTOPHER D. KOHARSKI | 3763 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 14 November 2008.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-8 and 21-24 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) 1-8 is/are allowed.
- 6) Claim(s) 21-24 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/14/2008</u> . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Response to Amendment

The Examiner acknowledges the reply filed 11/14/2008 in which claim 1, 2 and 21 were amended. Currently claims 1-8 and 21-24 are pending for examination. The Examiner also acknowledges the amended specification.

Information Disclosure Statement

The information disclosure statement (IDS) that was submitted on 11/14/2008 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner is considering the information disclosure statement.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 21-24 are rejected under 35 U.S.C 103(a) as being unpatentable over Mogensen et al. (US2003/0109829) in view of Hunn et al. (US2004/0158207). Mogensen et al. discloses an injector device for an infusion set.

Regarding claims 21-24, Mogensen et al. discloses a method for introducing an infusion set comprising uncapping the insertion device to place the insertion device in a delivery state wherein the device is placed adjacent to the skin, with a tamper evident seal placed (42) on the insertion device (Figures 1-5, [0028-0035]).

Mogensen et al. meets the claim limitations as described above except for automatically retracting and having a locked and unlocked infusion state.

Hunn et al. discloses an infusion set device for cannula insertion.

Regarding claims 21-24, Hunn et al. discloses a method for introducing an infusion device comprising an infusion device (1) onto a needle (8) of an insertion device so the needle extends through the cannula (3) of the infusion device whereby the system is placed adjacent the skin of a patient ([0073-0076]) wherein the cannula is manually introduced into the subcutaneous layer of skin of the patient by pressing a button (24) triggering the needle to move relative to coupled sleeve (6) which hides the needle (8) prior to retraction or insertion and then after insertion the needle mechanism can be configured to be automatically withdrawn (Figures 9-13) ([0077-0078]).

Additionally, an infusion device (2) includes a cannula (3) and method of coupling the system (Figures 1, 2 and 5) wherein positioning the assembly includes placing the set into a locked and unlocked state for fluid transfer ([0067-0068]).

At the time of the invention, it would have been obvious to include the automatic needle retraction and locking infusion set of Hunn et al. to the system of Mogensen et al. because the addition of an automatic needle retraction system and locking setup allows for ease of use and an increase in patient comfort. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Hunn et al. ([0001—0045]).

Allowable Subject Matter

Claims 1-8 are allowed.

Response to Arguments

Applicant's arguments filed 11/14/2008 have been fully considered but they are not persuasive. Applicant's Representative asserts that the combination of Mogensen et al. and Hunn et al. does not disclose the needle being moved without an automatic drive mechanism.

Examiner has fully considered applicant's arguments but they are not persuasive. It is examiners position that given a careful reading, the claims do not distinguish over the prior art of record.

The Examiner asserts that the prior art reference Hunn et al. (Figure 9) does not disclose an automatic drive mechanism. The insertion mechanism (24, 5, 27, 21) comprising a button, lever, and spring are manually activated via movement of the button. Although the movement is powered via a spring the activation is manual and therefore constitutes a manual system.

The prior art of record teaches all elements as claimed and these elements satisfy all structural, functional, operational, and spatial limitations currently in the claims. Therefore the standing rejections are proper and maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 5:30am to 2:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Date: 1/21/2009

/Christopher D Koharski/
Examiner, Art Unit 3763

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763